

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
3 April 2003 (03.04.2003)

PCT

(10) International Publication Number  
**WO 03/026720 A2**

(51) International Patent Classification<sup>7</sup>: **A61M**  
(21) International Application Number: **PCT/US02/23049**  
(22) International Filing Date: **19 July 2002 (19.07.2002)**  
(25) Filing Language: **English**  
(26) Publication Language: **English**  
(30) Priority Data:  
**60/324,434** **24 September 2001 (24.09.2001)** **US**  
(71) Applicant: **BECTON, DICKINSON AND COMPANY**  
[US/US]; 1 Becton Drive, Franklin Lakes, NJ 07417-1880  
(US).  
(72) Inventors: **LAU, Steven, Choon, Meng**; 1A Ontario  
Avenue #03-02, Singapore 576190 (SG). **CHUA, Chui,**  
**Khim**; 425 Choa Chu Kang Avenue 3, #09-154, Singa-  
pore 680425 (SG). **MOH, Yaohan**; 678 Chao Chu Kang  
Crescent #05-626, Singapore 680678 (SG).

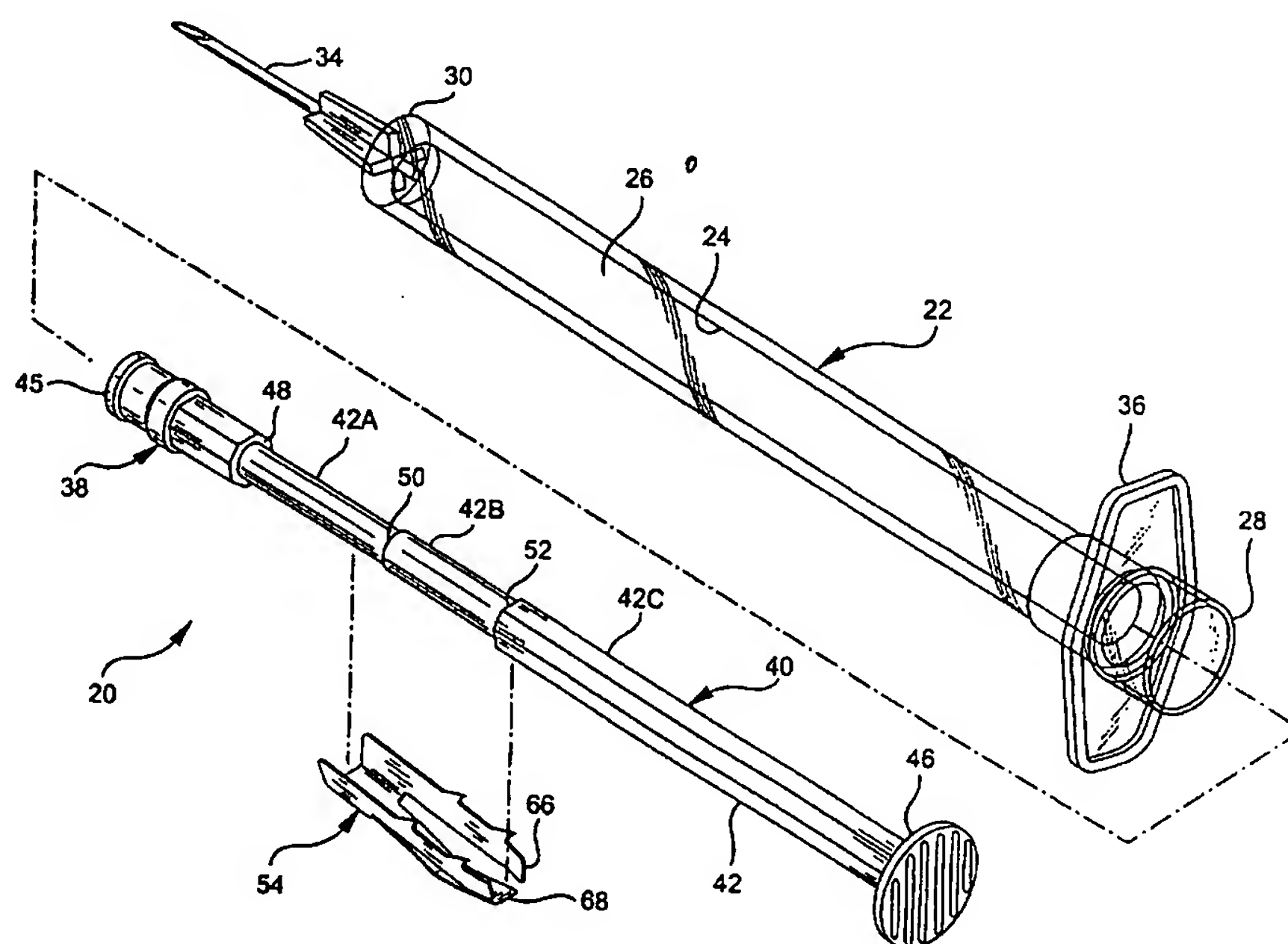
(74) Agent: **VOELLMICKE, John, L.**; Becton, Dickinson  
and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-  
1880 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,  
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,  
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,  
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,  
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,  
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN,  
YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,  
ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,  
TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,  
GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: **SINGLE USE SYRINGE AND PLUNGER ROD LOCKING DEVICE THEREFOR**



(57) Abstract: A single use syringe assembly is provided as well as a locking element for such an assembly. The single use syringe assembly includes a barrel, a plunger rod assembly and a locking element positioned within the barrel. The locking element includes one or more barbs for engaging the inside surface of the barrel. The barbs present the locking element from moving proximally within the barrel, but allow its distal movement therein with the plunger rod assembly. A spring member may be provided for urging the barbs towards the inside surface of the barrel. The barbs are preferably positioned on the edge portions of opposing legs that form part of the locking element.



WO 03/026720 A2



**Published:**

— without international search report and to be republished upon receipt of that report

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

SINGLE USE SYRINGE AND PLUNGER ROD  
LOCKING DEVICE THEREFOR

5

[0001] This Application claims benefit of U.S. provisional application no. 60/324,434 filed September 9, 2001.

BACKGROUND OF THE INVENTION

10 

Field of the Invention

[0002] The field of the invention relates to single use syringes and locking devices for locking the plunger assemblies of such syringes.

Brief Description of the Related Art

15 [0003] In the United States and throughout the world the multiple use of hypodermic syringe products that are intended for single use only is instrumental in drug abuse and more particularly in the transfer of contagious diseases. Intravenous drug users who routinely share and reuse syringes are a high risk group with respect to the AIDS virus. Also, the effects of multiple use are a major concern in third world  
20 countries where repeated use of syringe products may be responsible for the spread of many diseases. Reuse of single use hypodermic syringe assemblies is also instrumental in the spread of drug abuse even in the absence of infection or disease.

[0004] Many attempts have been made to remedy this problem. Some of these attempts have required a specific act to destroy the syringe after use either by using a  
25 destructive device or providing a syringe assembly with frangible zones so that the syringe could be rendered inoperable by the application of force. Other attempts have involved the inclusion of structure which would allow the destruction or defeating of the syringe function through a conscious act by the syringe user. Although many of these devices work quite well, they do require the specific intent of the user followed  
30 by the actual act to destroy or render the syringe inoperable. None of these devices is effective with a user having the specific intent to reuse the hypodermic syringe.

[0005] Single use hypodermic syringes that become inoperative or incapable of further use automatically without any additional act on the part of the user have been developed. One such syringe is disclosed in U.S. Patent No. 4,961,728. The syringe disclosed in this patent includes a locking element positioned in the syringe barrel. The locking element includes proximally and outwardly facing barbs that engage the inner surface of the syringe barrel and an inwardly facing driving edge adapted to interact with the plunger rod to move the locking element along the barrel as the stopper is advanced. The plunger rod includes a ledge positioned at a distance from the proximal side of a support wall that approximates the length of the locking element. The driving edge of the locking element engages the ledge, thereby ensuring that the locking element moves distally with the plunger rod and stopper.

[0006] U.S. Patent Nos. 5,021,047, 5,062,833 and 5,562,623 disclose single use syringes having plunger rods that have teeth or ridges and locking elements that engage the teeth or ridges. The locking elements of these syringes also include outwardly extending teeth or prongs that engage the inside surface of the syringe barrel. The plunger rods of these syringes can be retracted to draw fluid into the syringe barrel while the locking elements remain stationary. Distal movement of the plunger rods causes the fluid to be expelled, the locking elements moving distally with the plunger rods and substantially preventing further plunger rod retraction.

## SUMMARY OF THE INVENTION

[0007] A locking element for a single use syringe is provided. The locking element includes a base including a generally trough-shaped body having a longitudinal axis. A first leg extends from the base and is substantially parallel to the longitudinal axis. A second leg extends from the base in opposing relation to the first leg. Each leg includes one or more barbs. Each leg further includes an end portion that extends generally toward the longitudinal axis. A spring element is attached to the base for urging the barbs in a selected direction. The barbs are preferably located on the outer edges of the first and second legs.

[0008] A single use syringe assembly with a needle cannula in accordance with the invention includes a barrel having an inside surface defining a chamber for retaining fluid. The barrel has an open proximal end and a distal end having a

passageway in communication with the chamber. A plunger rod assembly is provided for use in conjunction with the barrel. The plunger rod assembly includes an elongate body portion having a proximal end, a distal end, and a stopper mounted to the elongate body portion proximate the distal end. The stopper is slidably positioned in substantially fluid tight engagement with the inside surface of the barrel. The elongate body portion of the plunger rod assembly extends outwardly from the open proximal end of the barrel. A generally trough-shaped locking element is positioned within the barrel. The locking element defines a channel through which the elongate body portion of the plunger rod assembly extends. One or more barbs extend from the locking element. The barbs engage the inside surface of the barrel for substantially preventing the locking element from moving proximally with respect to the barrel. The locking element also engages the elongate body portion of the plunger rod assembly such that the locking element is movable towards the distal end of the barrel as the plunger rod assembly is advanced. A spring member is attached to the locking element and urges the one or more barbs towards the inside surface of the barrel.

[0009] A single use syringe assembly is further provided that includes a barrel having an inside surface defining a chamber for retaining fluid, a plunger rod assembly, a needle cannula for hypodermic injection, and a locking element. The plunger rod assembly includes an elongate body portion having a proximal end, a distal end and a stopper mounted to the elongate body portion. The stopper is slidably positioned in substantially fluid tight engagement with the inside surface of the barrel. The locking element is positioned within the barrel. It includes first and second opposing walls and a third wall that connects them. A first leg extends from the first wall and a second leg extends from the second wall. A first barb extends from the first leg of the locking element while a second barb extends from the second leg thereof. It will be appreciated that one or more barbs may extend from the legs of the locking element. Each leg includes an end portion engageable with the body portion of the plunger rod assembly. The locking element can accordingly be moved distally with the plunger rod assembly along the syringe barrel. The barbs substantially prevent the locking element from moving proximally therein.



## BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Fig. 1 is an exploded, perspective view showing a single use syringe assembly according to the invention;

[0011] Fig. 2 is a top perspective view of the syringe assembly prior to use;

5 [0012] Fig. 3 is a top perspective view showing the syringe assembly following retraction of the plunger rod assembly thereof;

[0013] Fig. 4 is a cross-sectional view of the syringe assembly with the plunger rod assembly in the position shown in Fig. 2;

10 [0014] Fig. 5 is a cross-sectional view thereof showing the plunger rod assembly in the position shown in Fig. 3;

[0015] Fig. 6 is a cross-sectional view thereof showing the plunger rod assembly in a locked position following the injection stroke;

[0016] Fig. 7 is a cross-sectional view of the syringe of Fig. 4 taken along line 7-7.

15 [0017] Fig. 8 is a top plan view of a preform of a locking element;

[0018] Fig. 9 is a top plan view of a locking element for the single use syringe assembly;

[0019] Fig. 10 is a side elevation view of the locking element, and

[0020] Fig. 11 is an end view of the locking element.

20

## DETAILED DESCRIPTION OF THE INVENTION

[0021] There is shown in the drawings and will be described in detail herein a preferred embodiment of the invention with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to limit the invention to the embodiment illustrated.

25

[0022] Referring first to Figs. 1-3, a single use syringe assembly 20 includes a barrel 22 having an inside surface 24 defining a chamber 26 for retaining fluid. The barrel 22 includes an open end 28 and a distal end 30 having a passageway 32 therethrough in communication with the chamber. A needle cannula 34 projects outwardly from the distal barrel end. The needle cannula has a lumen (not shown) therethrough in fluid communication with the passageway and a sharpened distal tip. The syringe assembly of the present invention is preferably used with a needle

30

cannula that is attached to the distal end of the barrel by an adhesive or other suitable means. It will be appreciated that the invention could be applied to syringe assemblies having removable needle/hub assemblies, or fixed or removable blunt cannulas.

5           [0023] As used in the preceding paragraph and hereafter, the term “distal end” refers to the end furthest from the person holding the syringe assembly. The term “proximal end” refers to the end closest to the holder of the syringe assembly. In the preferred embodiment, the proximal end of the barrel 22 includes a flange 36 to facilitate handling and positioning of the syringe assembly and to maintain the relative  
10 position of the barrel with respect to the plunger rod during filling and medication administration.

          [0024] A plunger assembly 38 includes a plunger rod 40 having an elongate body portion 42. The distal end of the elongate body portion includes a projection having an enlarged end 44. A stopper 45 having a recess therein is affixed to this end.  
15 A disc-shaped flange 46 is provided at the proximal end of the plunger rod for allowing the user to apply the force necessary to move the plunger rod with respect to the barrel. The elongate body portion 42 includes several sections between the proximal and distal ends thereof. A first section 42A thereof is substantially cylindrical. The distal end of this section adjoins an enlarged plunger rod surface that  
20 functions as a stop surface 48 as described hereafter. A second section 42B adjoins the proximal end of the first section, and is also substantially cylindrical. The second section is larger in diameter than the first section, and accordingly defines a shoulder 50 at the proximal end of the first section. A third section 42C extends between the second section 42B and the disc-shaped flange 46. A second shoulder 52 adjoins the  
25 proximal end of the second section 42B, and separates the second and third sections.

          [0025] A locking element 54 is positioned within the barrel 22. In accordance with the preferred embodiment, the locking element is generally trough-shaped. The locking element defines a channel through which the elongate body portion 42 of the plunger rod 40 extends. It will be appreciated that the locking element can be U-  
30 shaped in cross section or otherwise similarly configured, all of which should be considered generally trough-shaped as the term is used herein.

[0026] The locking element includes a base 56 that includes a bottom wall 58 and first and second opposing side walls 60, 62. A first leg 64 extends proximally from the first wall and a second leg 66 extends proximally from the second wall. The legs 64, 66 are also in opposing relation. A spring element 68 in the form of a third leg extends proximally from the bottom wall 58.

[0027] Each of the legs 64, 66 includes an end portion that is angled generally towards a longitudinal axis extending through the channel defined by the locking element. They further include inner and outer edges. (The terms "inner" and "outer" are relative terms as used herein.) The inner edges thereof are substantially adjacent to the spring element. Barbs 70, 72 are integral with the outer edges of the first and second legs. The spring element 68 includes a pair of bends 68A, 68B therein. It accordingly extends beneath the plane of the bottom wall 58 of the base 56, as best shown in Fig. 10.

[0028] The locking element is preferably formed from a thin sheet of metal such as stainless steel. It is preformed into the flat configuration shown in Fig. 7. The broken lines show the folds that are made in the flat substrate 74 to form the locking element 54 shown in Figs. 7 and 9-11. The dimensions of the locking element are selected in accordance with the barrel and plunger rod assembly with which it is to be used.

[0029] The syringe assembly is easily constructed from the component parts thereof. The locking element is positioned on the section 42B of the plunger rod 40 such that the angled end portion of the legs 64, 66 adjoin the shoulder 52 at the proximal end of this section. The legs 64, 66 and spring member extend proximally, and the barbs 70, 72 are angled proximally with respect to the plunger rod. The plunger rod/locking element assembly is then inserted into the barrel 22 through the proximal end thereof. As the assembly is moved distally within the barrel, the angular orientation of the barbs allows them to slide along while engaging the inside surface 24 of the barrel. The locking element moves distally with the plunger rod due to the engagement of the ends of the legs 64, 66 with the shoulder. The plunger rod/locking element assembly is moved distally to the positions shown in Figs. 2 and 4 where the stopper engages the end wall of the barrel. The syringe assembly is then ready for use or storage.



[0030] In use, the plunger rod assembly 38 is retracted from the position shown in Fig. 4 to the position shown in Fig. 5 in order to draw fluid through the needle cannula 34 and passageway 32 and into the chamber 26 of the barrel 22. The locking element 54 remains stationary during such retraction, and the plunger rod assembly is moved proximally with respect to both the barrel 22 and the locking element. This is due to the engagement of the barbs 70, 72 with the inside surface 24 of the barrel. The barbs are preferably made from a harder material than the barrel, which enhances their ability to resist proximal movement. The barbs are resiliently urged by the spring member towards the inside surface 24 of the barrel, further enhancing their effectiveness.

[0031] Retraction of the plunger rod assembly 38 is limited by the locking assembly. As shown in Fig. 5, the stop surface 48 on the plunger rod 40 engages the distal end of the locking element 54. As the locking element cannot be moved proximally, further retraction of the plunger rod assembly is not possible. The amount of fluid that can be drawn into the chamber 26 is accordingly limited by the distance between the stop surface 48 and the second shoulder 52 as well as the length of the locking element. It will be appreciated that the distance between the stop surface 48 and second shoulder 52 and the length of the locking element 54 can be chosen to meet the needs of particular applications.

[0032] The end portions of the legs 64, 66 of the locking element adjoin the first shoulder 50 when the plunger rod assembly is retracted to the position shown in Fig. 5. The distance between the first shoulder 50 and the stop surface 48, being substantially the same as the distance between the distal end of the locking element and the proximal end portions of the legs, causes the locking element to be substantially immovable with respect to the plunger rod assembly. As discussed above, the locking element is substantially immovable in the proximal direction within the barrel due to the engagement of the barbs 70, 72 with the inside surface of the barrel 22.

[0033] Once the fluid has been drawn into the barrel from a vial or other fluid source, the needle cannula can be removed from the fluid source and used for injection. During the injection of a patient, the plunger assembly 38 and locking element both move distally from the positions shown in Fig. 5 to the positions shown

in Fig. 6. In Fig. 6, the stopper 45 again adjoins or engages the end wall of the barrel 22. The locking element 54 remains positioned between the stop surface 48 and the first shoulder 50. Both the plunger rod assembly 38 and the locking element are substantially immovable from their positions. The syringe assembly 20 accordingly cannot be reused.

[0034] The syringe barrel of the present invention may be constructed of a wide variety of rigid materials with thermoplastic materials such as polypropylene and polyethylene being preferred. Similarly, thermoplastic materials such as polypropylene, polyethylene and polystyrene are preferred for the plunger rod. A wide variety of materials such as natural rubber, synthetic rubber and thermoplastic elastomers are suitable for the stopper. The choice of stopper material will depend on compatibility with the medication being used. In the preferred embodiment of this invention, the stopper 45, made of medical grade rubber, includes a partially hollow interior with an undercut ledge which is snap fit over complementary structure 44 on plunger rod 40 to secure the stopper to the plunger rod. The stopper and plunger rod may also be integrally formed of the same material or different materials, or secured together in other suitable ways.

[0035] As previously recited, it is preferable that the locking element be fabricated from a material which is harder than the barrel so that the locking barbs may effectively engage the barrel. Resilient spring like properties are also desirable along with low cost dimensionally consistent fabrication. With this in mind, sheet metal is the preferred material for the locking element with stainless steel being preferred for medical applications. Although the locking element of the preferred embodiment is fabricated from a single sheet, it is within the purview of the instant invention to include locking elements made of other forms and/or containing multiple parts and materials.

[0036] Thus, it can be seen that the present invention provides a simple, reliable, easily fabricated, single use syringe which becomes inoperable or incapable of further use without any additional act on the part of the user.

## WHAT IS CLAIMED IS:

1. A locking element for a single use syringe, comprising:
  - a base including a generally trough-shaped body having a longitudinal axis;
  - a first leg extending from said base substantially parallel to said longitudinal
  - 5 axis;
  - a second leg extending from said base substantially parallel to said longitudinal axis, said second leg being in opposing relation to said first leg;
  - a first barb extending from said first leg;
  - a second barb extending from said second leg;
  - 10 said first leg including a first end portion extending generally towards said longitudinal axis;
  - said second leg including a second end portion extending generally towards said longitudinal axis, and
  - a spring element for urging said barbs in a selected direction, said spring
  - 15 element attached to said base.
2. A locking element as described in claim 1 wherein said base, legs and spring element are of integral construction and formed from a substantially flat, integral sheet of metal.
- 20 3. A locking element as described in claim 1 wherein each of said first and second legs include an inner edge and an outer edge, said first and second barbs extending, respectively, from said outer edges of said first and second legs.
- 25 4. A locking element as described in claim 3 wherein said spring element includes a third leg extending between said first and second legs and adjacent to said inner edges thereof.
- 30 5. A locking element as described in claim 4 wherein said third leg is pivotably attached to said base.

6. A locking element as described in claim 5 wherein said third leg has a bend therein.

7. A single use syringe assembly comprising:

5 a barrel having an inside surface defining a chamber for retaining fluid, and open proximal end and a distal end having a passageway in communication with said chamber;

10 a plunger rod assembly including an elongate body portion having a proximal end, a distal end, and a stopper mounted to said elongate body portion proximate said distal end, said stopper being slidably positioned in substantially fluid tight engagement with said inside surface of said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel; and

15 a generally trough-shaped locking element positioned within said barrel, said locking element defining a channel, said elongate body portion of said plunger rod assembly extending through said channel;

one or more barbs extending from said locking element, said one or more barbs engaging said inside surface of said barrel for substantially preventing said locking element from moving proximally with respect to said barrel but allowing movement of said locking element towards said distal end;

20 said locking element engaging said elongate body portion of said plunger rod assembly such that said locking element is movable towards said distal end of said barrel as said plunger rod assembly is advanced, and

a spring member attached to said locking element and urging said one or more barbs towards said inside surface of said barrel.

25

8. A single use syringe assembly as described in claim 7 wherein said locking element includes first and second edges, said one or more barbs extending from said edges, and said spring member being integral with said locking element.

30 9. A single use syringe assembly as described in claim 8 wherein said elongate body portion of said plunger rod assembly includes first and second adjoining portions, said first portion being distal of said second portion and having a

smaller diameter than said second portion, a first shoulder separating said first and second portions, and a stop surface at the distal end of said first portion, said locking element having a distal end engageable with said stop surface and a proximal end engageable with said first shoulder.

5

10. A single use syringe assembly as described in claim 9 wherein said locking element includes a base and first and second legs extending from said base, said first and second legs being in substantially opposing relation and having end portions engageable with said elongate body portion of said plunger rod, said spring member comprising a third leg extending from said base between said first and second legs.

10

11. A single use syringe assembly as described in claim 10 wherein said first and second legs include inner edges adjoining said third leg and outer edges, said outer edges of said first and second legs including one or more barbs.

15

12. A single use syringe assembly comprising:  
a barrel having an inside surface defining a chamber for retaining fluid;  
a plunger rod assembly including an elongate body portion having a proximal end, a distal end and a stopper mounted to said elongate body portion, said stopper being slidably positioned in substantially fluid tight engagement with said inside surface of said barrel, said elongate body portion extending outwardly from said barrel;

20

a locking element positioned within said barrel, said locking element including a base including first and second opposing walls and a third wall connecting said first and second walls, a first leg extending proximally from said first wall, a second leg extending proximally from said second wall, said first and second legs being in opposing relation, a first barb extending from said first leg and engaging said inside surface of said barrel, a second barb extending from said second leg and engaging said inside surface of said barrel, said first leg including a first end portion engageable with said elongate body portion of said plunger rod assembly, said second leg including a second end portion engageable with said elongate body portion of said

25

30



plunger rod assembly, said first and second barbs being positioned to substantially prevent said locking element from moving proximally in said barrel, but allowing said locking element to move distally within said barrel.

5           13.     A single use syringe as described in claim 12 including means for resiliently urging said first and second barbs towards said inside surface of said barrel.

10           14.     A single use syringe as described in claim 13 wherein said means for resiliently urging including a third leg extending proximally from said third wall of said base, each of said first and second legs includes a substantially flat body having an inner edge substantially adjacent to said third leg and an outer edge, said first and second barbs extending, respectively, from said outer edges of said first and second legs.

15           15.     A single use syringe as described in claim 14 wherein said locking element has a generally trough-shaped configuration.

20           16.     A single use syringe as described in claim 15 wherein said elongate body portion of said plunger rod assembly includes first and second adjoining portions, said first portion being distal of said second portion and having a smaller diameter than said second portion, a first shoulder separating said first and second portions, and a stop surface at the distal end of said first portion, said first and second inwardly extending end portion of said first and second legs being engageable with said first shoulder, said locking element being engageable with said stop surface.

25

17.     A single use syringe as described in claim 16 wherein said elongate body portion of said plunger rod assembly includes a second shoulder proximal of said first shoulder, said end portions of said first and second legs being engageable with said second shoulder.

30

18. A single use syringe as described in claim 17 wherein the distance between said first shoulder and said stop surface is substantially the same as the length of said locking element.

5 19. A single use syringe as described in claim 18 wherein said locking element is formed from a substantially flat, integral sheet of metal.

20. A single use syringe as described in claim 12 wherein said locking element is formed from a substantially flat, integral sheet of metal.

10

21. A single use syringe as described in claim 20 including a spring member extending proximally from said base and urging said barbs towards said inside surface of said barrel, wherein each of said first and second legs includes a substantially flat body having inner and outer edges, said first and second barbs extending, respectively, from said outer edges of said first and second legs, said inner edges of said first and second legs being adjacent to said spring member.

15

22. A single use syringe as described in claim 21 wherein said locking element has a generally trough-shaped configuration.

20

23. A single use syringe as described in claim 21 wherein said spring member includes a third leg extending proximally from said third wall of said base, said third leg including a bend therein.

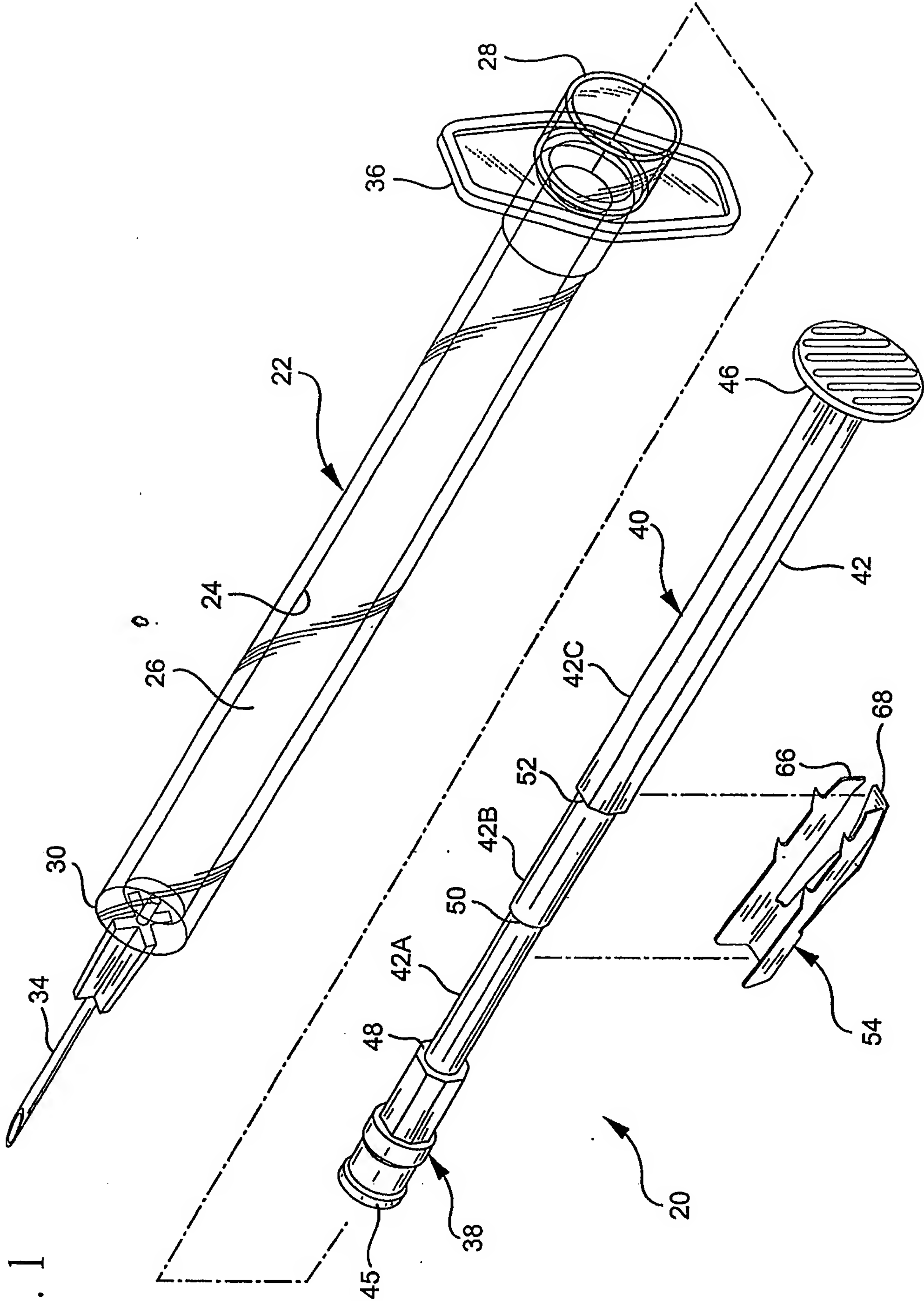


FIG. 1

FIG. 2

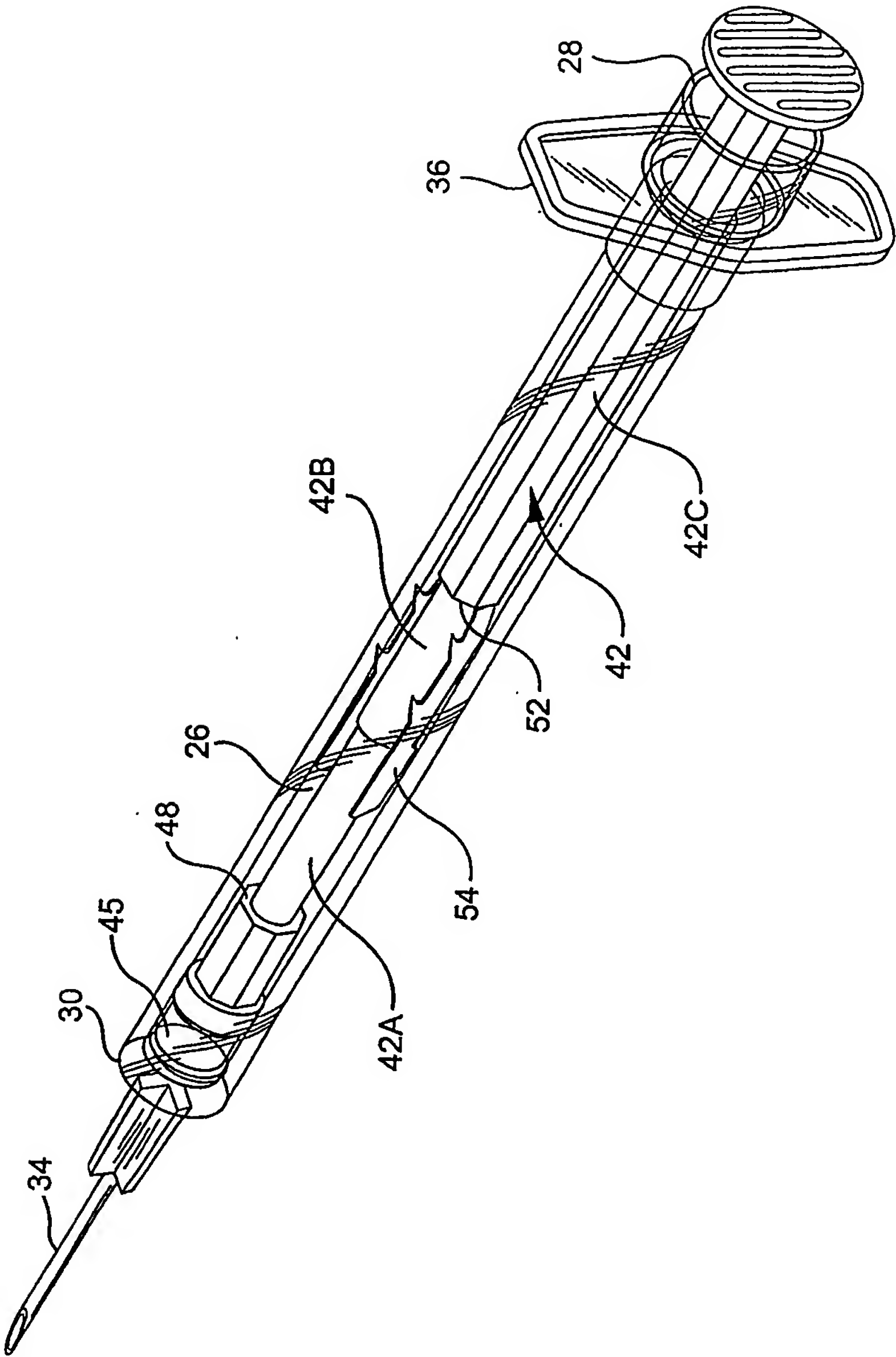


FIG. 3

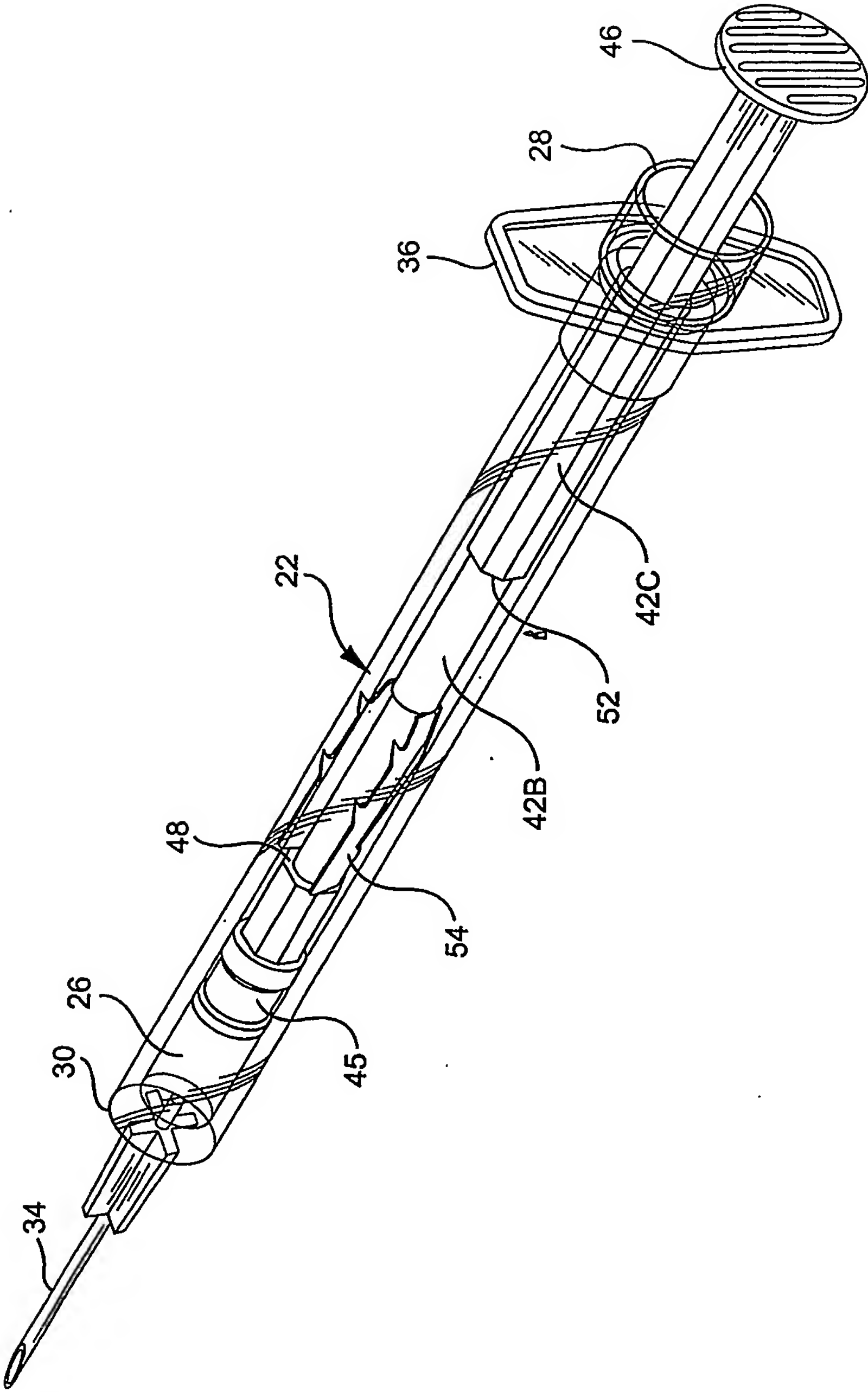




FIG. 4

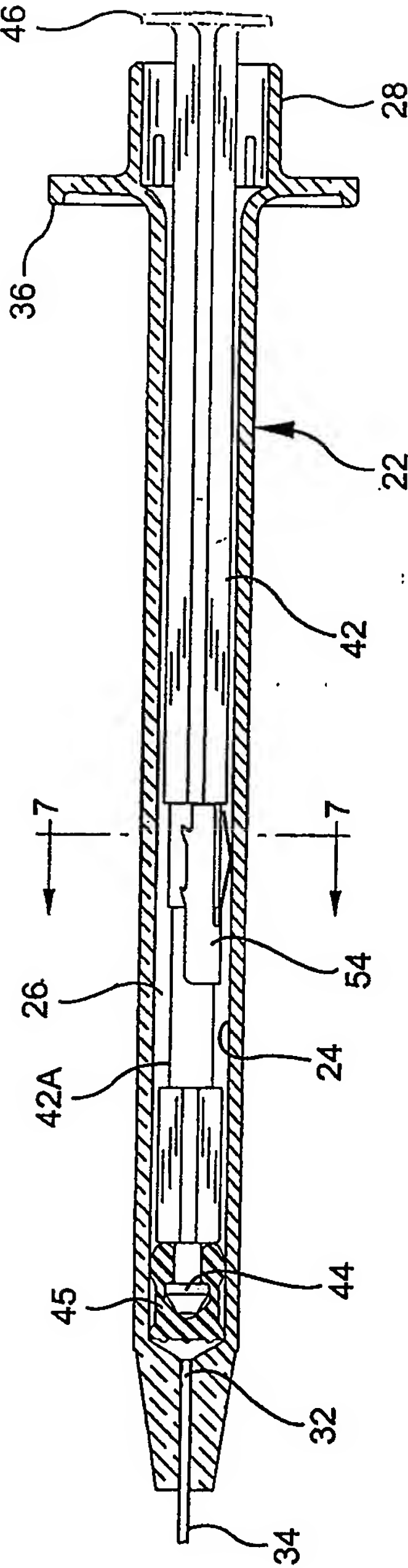


FIG. 5

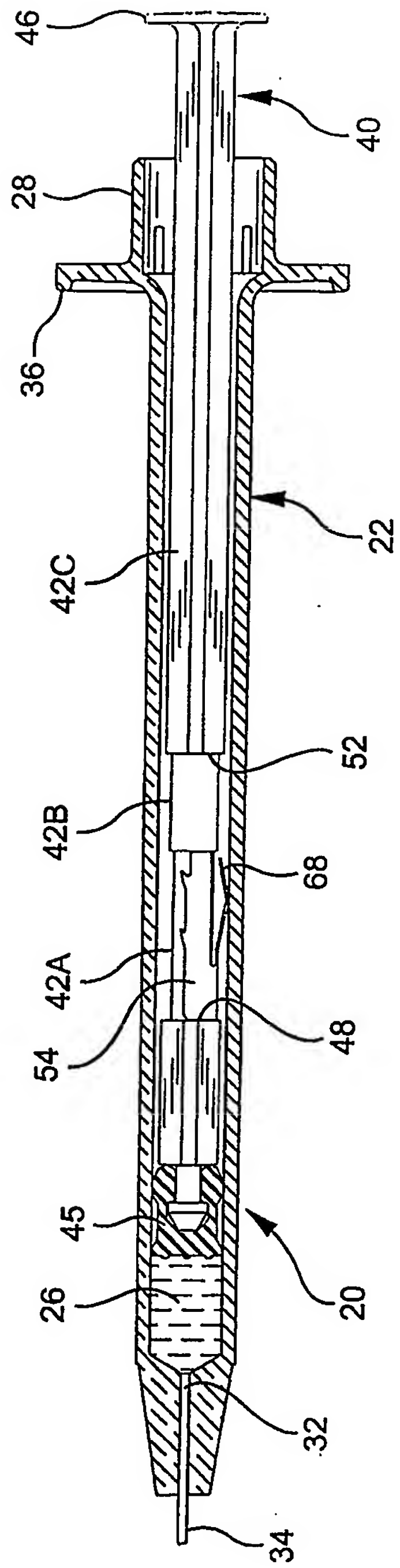
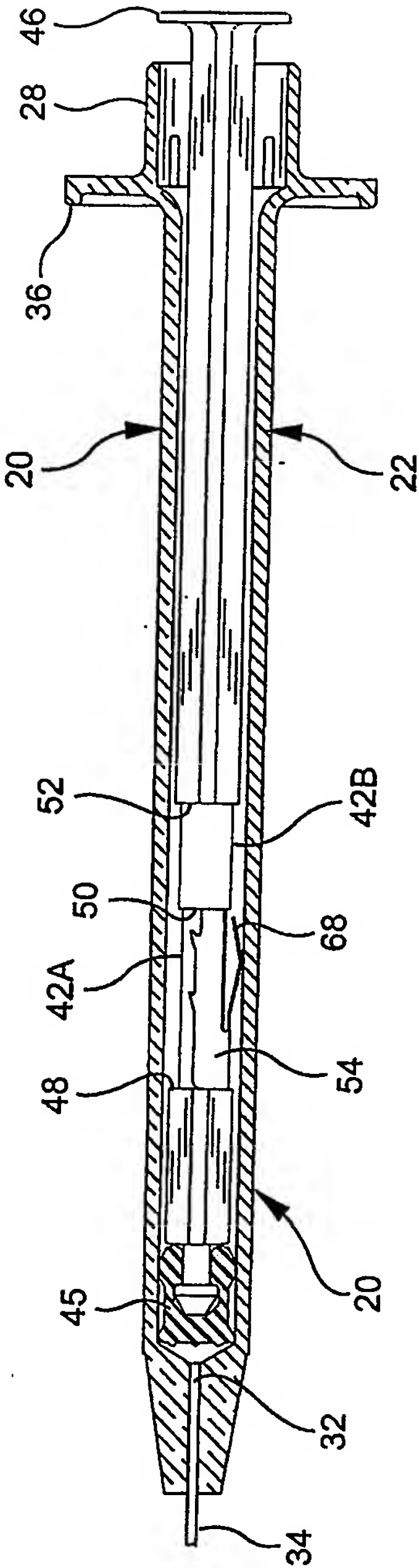


FIG. 6



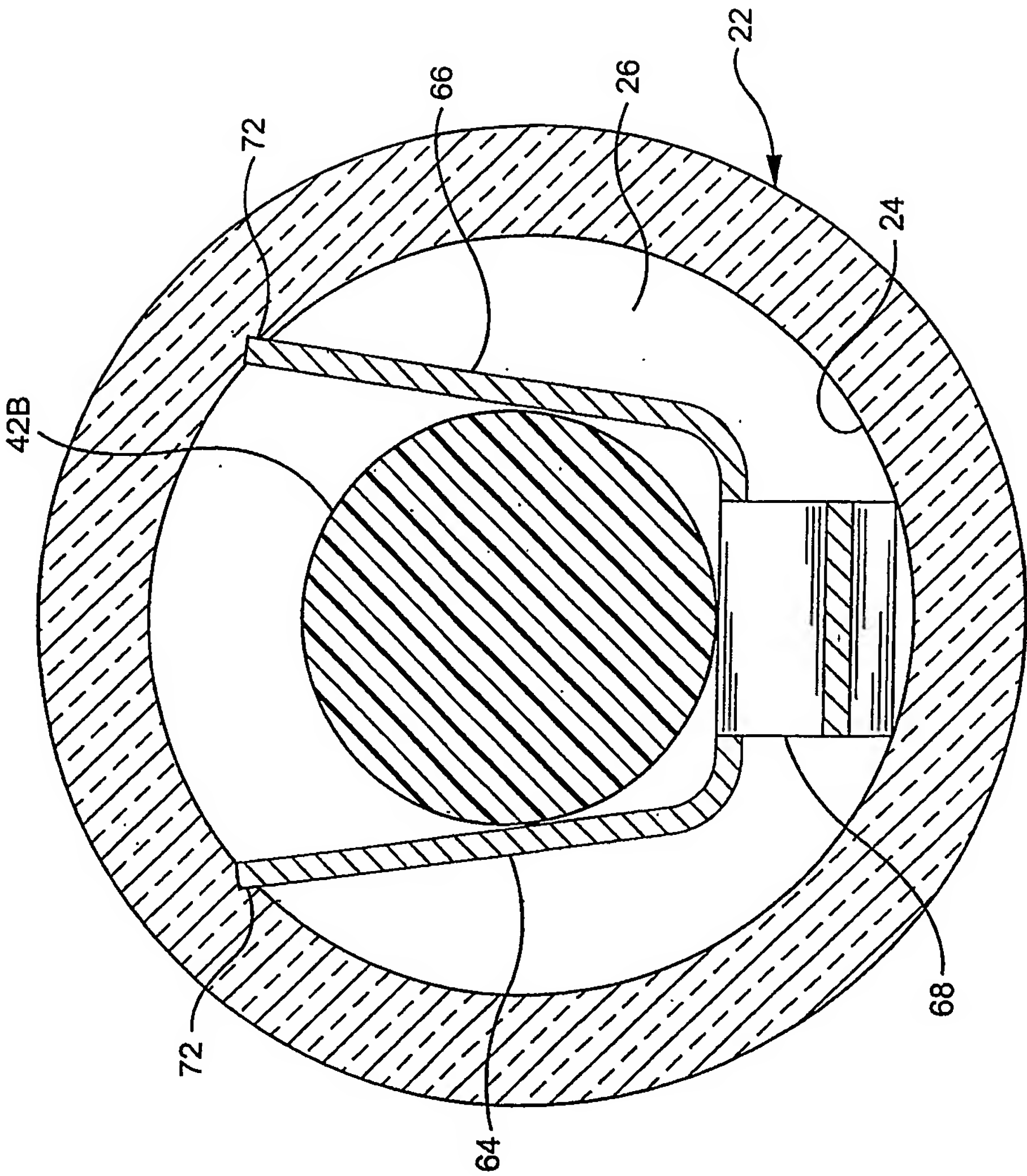


FIG. 7

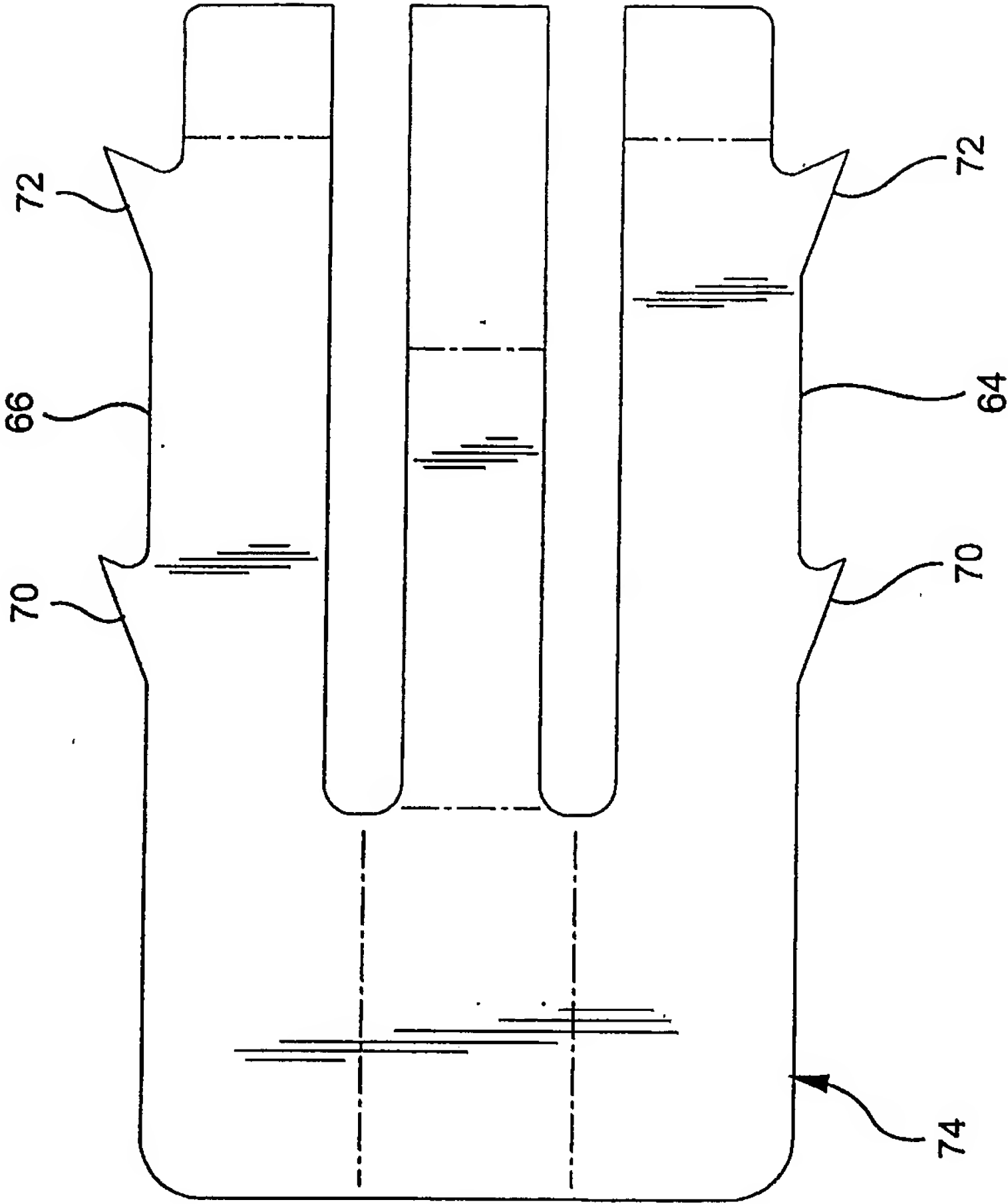


FIG. 8



FIG. 9

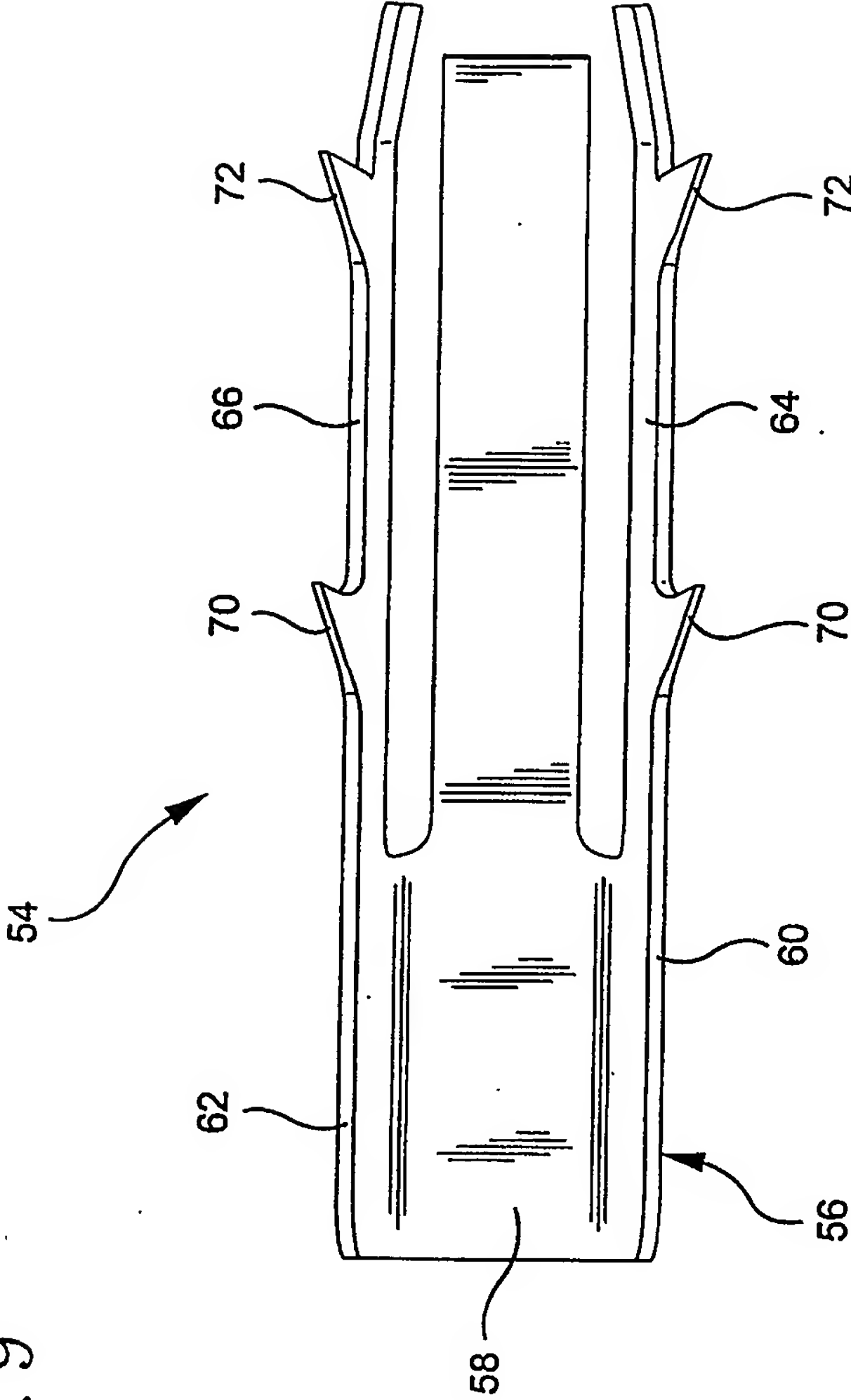


FIG. 10

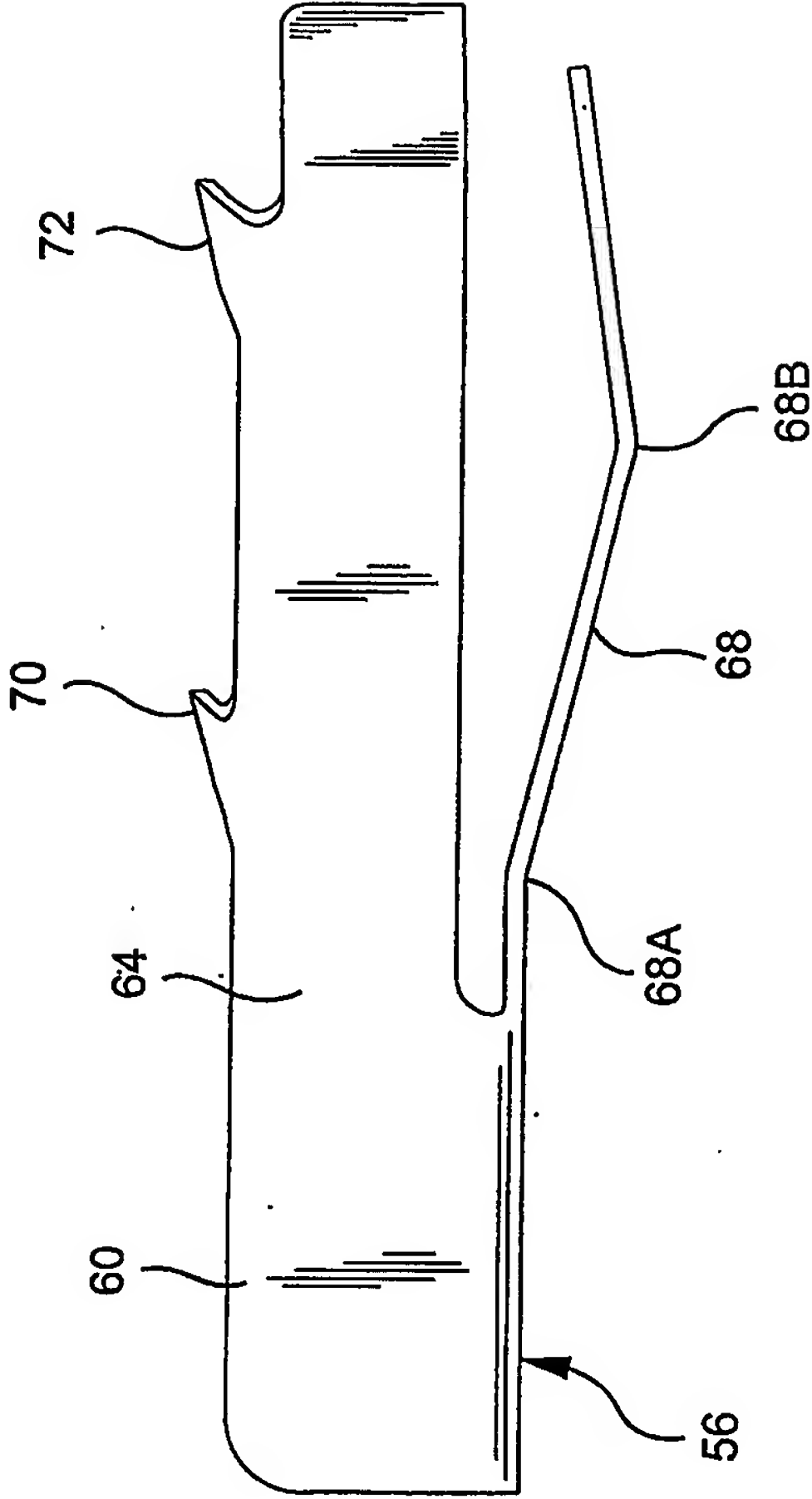


FIG. 11

